REMARKS/ARGUMENTS

The Pending Claims

Claims 1-8, 16, 17, and 19-23 currently are pending. The claims are directed to a nutrition trace element composition comprising selenium and zinc, and a method of using the composition.

The Amendments to the Claims

Claim 23 has been amended to recite that the composition comprises electrolyte *concentrates* exclusively. This amendment is supported by the specification at, e.g., page 1, lines 8-9. No new matter has been added by way of this amendment.

The Office Action

The Office Action rejects claim 23 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description. The Office Action rejects claims 1, 8, 16, 17, and 19-23 under 35 U.S.C. § 103(a) as allegedly obvious over Frankel ("Supplementation of Trace Elements in Parenteral Nutrition: Rationale and Recommendations"), alone or in combination with Ballevre et al. (U.S. Patent Application Publication 2003/0161863). Reconsideration of these rejections is respectfully requested.

Discussion of Written Description Rejection

Claim 23 is rejected under Section 112, first paragraph, because the specification allegedly does not support the phrase "containing electrolytes exclusively." Rather, the Office Action contends that the specification supports the phrase "containing electrolyte *concentrates* exclusively." While it would be clear to one of ordinary skill in the art that the specification discloses a composition that contains *electrolytes* exclusively, claim 23 has been amended to recite electrolyte *concentrates*. Accordingly, the rejection under Section 112, first paragraph, should be withdrawn.

Discussion of Obviousness Rejection

Claims 1, 8, 16, 17, and 19-23 have been rejected under Section 103(a) as allegedly obvious over Frankel alone or in combination with Ballevre et al. These rejections are traversed for the reasons set forth below.

For subject matter defined by a claim to be considered obvious, the Office must demonstrate that the differences between the claimed subject matter and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a); see also *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). The ultimate determination of whether an invention is or is not obvious is based on certain factual inquiries including: (1) the scope and content of the prior art, (2) the level of ordinary skill in the prior art, (3) the differences between the claimed invention and the prior art, and (4) objective evidence of nonobviousness. *Graham*, 383 U.S. at 17-18, 148 U.S.P.Q. at 467.

Consideration of the aforementioned Graham factors here indicates that the present invention, as defined by the pending claims, is unobvious in view of the cited references.

Regarding the scope and content of the prior art, Frankel discloses compositions for total parenteral nutrition (TPN) therapy. In particular, Frankel recommends supplementation of chromium, copper, manganese, selenium, and zinc for most patients on TPN. Frankel recommends a "minimum provision" of 50 mcg/day (i.e., 0.05 mg/day) of selenium (Frankel at page 587, fourth paragraph). Frankel recommends a minimum of 5 mg/day of zinc, and discloses that as much as 10 mg/day of zinc can be provided. Ballevre et al. discloses an enteral nutrition composition comprising micronutrients, including selenium and zinc, but excluding iron. Specifically, the composition can comprise about 5 mg-about 10 mg zinc, and about 40 μg-about 100 μg (i.e., about 0.04 mg-about 0.1 mg) selenium.

For the sake of argument and for purposes of the present analysis, one of ordinary skill in the art can be assumed to be someone with an advanced degree in a relevant field and a few years of experience in the relevant art.

Claims 1 and 16 require a nutrition trace element composition which contains 0.5 mg-2 mg of selenium and 10 mg-100 mg of zinc in one daily dose of the composition. While Frankel discloses compositions comprising a broad range of selenium and zinc concentrations which arguably overlap or touch the ranges recited in the pending claims, Frankel does not disclose the claimed ranges with sufficient specificity to lead one of ordinary skill in the art to choose the claimed selenium or zinc concentrations. In this respect, Frankel discloses administering at least 50 mcg/day of selenium, but does not disclose a recommended maximum dose. In addition, Frankel discloses administering a minimum of 5 mg/day of zinc, but that as much as 10 mg/day of zinc could be useful.

Ballevre et al. discloses an enteral nutrition composition comprising micronutrients, including selenium and zinc, but excluding iron. Specifically, the composition can comprise about 5 mg-about 10 mg zinc, and about 40 μg-about 100 μg (i.e., about 0.04 mg–about 0.1 mg) selenium. Ballevre et al., however, does not disclose a composition comprising 0.5 mg-2 mg of selenium.

Furthermore, Applicants have previously demonstrated that the claimed invention involves surprising and unexpected results (see Rule 132 Declaration of D. Thomas Stiefel dated December 28, 2009). In particular, Applicants clearly demonstrated that compositions comprising high doses of selenium and zinc which are encompassed by the claims (i.e., selenium doses that are ten-fold higher than those disclosed in the prior art), are associated with a low risk of chronic inflammation, infections, or diseases associated with free-radical production, as compared to low-dose compositions.

However, the Office Action contends that the Rule 132 declaration does not provide an adequate factual showing of unexpected results because the tested samples described therein are not commensurate in scope with rejected claims. The Office Action also contends that the comparison samples described in the declaration do not represent the closest prior art. Applicants respectfully disagree with both contentions by the Examiner.

Applicants remind the Office that evidence submitted to rebut a *prima facie* case of obviousness must be *reasonably* commensurate in scope with the claimed invention. When considering whether such evidence is commensurate in scope with the claimed invention, Applicants are not required to show unexpected results over the *entire* range of properties

possessed by a chemical compound or composition (see, e.g., M.P.E.P. § 2145, and *In re Chupp*, 816 F.2d 643, 646, 2 U.S.P.Q. 2d 1437, 1439 (Fed. Cir. 1987)). Indeed, evidence that a compound or composition possesses superior and unexpected properties in "one of a spectrum" of properties can be sufficient to rebut a *prima facie* case of obviousness. *Id.* Moreover, if the evidence is deemed insufficient to rebut the *prima facie* case of obviousness, the Office must specifically set forth the facts and reasoning that justify this conclusion (M.P.E.P. § 2145).

Applicants submit that the results described in the previously submitted Rule 132 declaration are reasonably commensurate in scope with the rejected claims. With respect to the comparison samples, the comparison drug described in the declaration (i.e., Tracutil®) comprises a daily dose of 20 mg selenium and 3.27 mg zinc. Applicants submit that this dose is reasonably commensurate in scope with the closest prior art (i.e., Frankel, which discloses a composition comprising a daily dose of at least 0.05 mg selenium and as much as 10 mg of zinc).

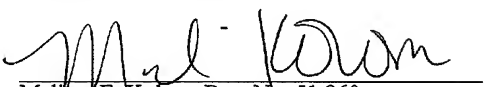
Nevertheless, Applicants submit herewith a second Declaration under 37 C.F.R. § 1.132 of Dr. Thomas Stiefel, which confirms that, contrary to the Office's assertion, the limitations of the commercially-available treatments for selenium deficiency were unknown to those of ordinary skill in the art at the time the application was filed. Rather, as described in the second Rule 132 Declaration, it was the present inventor who was the first to identify deficiencies in the conventional recommendations for selenium and zinc substitution. The second Rule 132 Declaration also confirms that the presently claimed composition comprises dosages of selenium and zinc that are well beyond the recommendations in the prior art and the levels in selenium supplement compositions commercially available at the time of the filing of the present application. Surprisingly, this increased dose produces normal levels of selenium in the blood and serum of patients and does not induce toxic side-effects.

In view of the foregoing, the present invention must be considered unobvious over the combination of the cited references. Accordingly, Applicants request that the rejection under Section 103(a) be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

Respectfully submitted,



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